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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,778	03/12/2001	Bridget Kathleen Mapleson	1324.024A	9665

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EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,778

Applicant(s)

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The response filed on 2-4-2002 is acknowledged. Claims 1-5 and 7-20 are pending and currently under examination.

Claim Rejections Withdrawn

The rejection of claims 1-5 under 35 U.S.C. 102(b) as being clearly anticipated by Shanbrom et al. (EP 0 083 999) is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

The rejection of claims 1-6 and 7-20 (recited by the examiner as claims 1-19 in the previous Office action) under 35 U.S.C. 103(a) as being unpatentable over Shanbrom et al. (EP 0 083 999) in view of McIntire et al. (Biochemistry Vol. 8, October 1969, pages 4063-66) and Schindler et al. (Journal of Immunological Methods, September 1989, pages 159-165) is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is rendered vague and indefinite by the use of the phrase "ionic surfactant effective to dissociate the endotoxin from the amphiphilic...". It is unclear what is meant by said phrase. Is applicant referring to any surfactant that causes dissociation at any concentration or is applicant referring to an effective concentration.

Claims 1-4 are rendered vague and indefinite by the use of the term "vaccine substance". How does a "vaccine substance" differ from a vaccine?

Claim 4 is rendered vague and indefinite by the use of the term "vaccine antigen". How does a "vaccine substance" differ from a "vaccine antigen"?

Claim 5 recites the limitation "the antigen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is rendered vague and indefinite by the use of the term "analogue". There is no clear definition of ^{what} constitutes an analogue. What function or structure must be maintained in order to be considered an analogue?

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanbrom (EP 0 083 999) in view of Shanbrom (U.S. Patent 4,315,919).

The instant claims are drawn to a method of removing bacterial endotoxin from a pharmaceutical process solution comprising treating the solution with an **ionic** surfactant effective to dissociate the endotoxin from the vaccine or pharmaceutical drug being purified and then filtering the solution through a molecular weight cut off filter having a pore size effective to retain said vaccine or pharmaceutical drug but allow the endotoxin to pass through. Said vaccine substance can be a polypeptide, glycoprotein or a viral (influenza) antigen. Said surfactant can be ionic, anionic or a bile salt (deoxycholate). Said cut off filter can be a regenerated cellulose acetate membrane or a polysulfone membrane.

Shanbrom (EP 0 083 999) discloses a method of purifying biological, pharmaceutical and biomedical products comprising contacting said product with a non-denaturing surfactant (see pages 5-7). Shanbrom further discloses the use of ultrafiltration techniques (including dialysis) to separate the biomedical product from surfactant and dissociated impurities (see page 10). Shanbrom discloses that his method can be used for purifying both proteinaceous (see page 5)

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and non-proteinaceous (see page 7) products. Shanbrom differs from the claimed invention in that he does not explicitly disclose the use of ionic surfactants such as deoxycholate or the use of filters comprising regenerated cellulose acetate membrane or a polysulfone membrane.

Shanbrom (U.S. Patent 4,315,919) disclose a method of removing pyrogens (endotoxins) from biological and biomedical products utilizing a myriad of surfactants (see columns 1-5). Said surfactants include cationic, anionic, ampholytic and nonionic surfactants (see column 1, line 48 to column 2, line 50) Said surfactants also include salts of bile acids including sodium deoxycholate. Shanbrom further discloses that it might be necessary to separate the purified product from the surfactant and impurities (see column 3, line 67 to column 4, line 2).

Consequently, it would have been obvious to one of ^{ordinary} skill in the art to utilize the various surfactants disclosed by Shanbrom (U.S. Patent 4,315,919) in the methods disclosed by Shanbrom (EP 0 083 999) since Shanbrom (EP 0 083 999) discloses the use of all non-denaturing surfactants (see page 5, lines 13-14) and Shanbrom (U.S. Patent 4,315,919) merely lists various non-denaturing surfactants. It should be noted that neither Shanbrom reference explicitly disclose the use of filters comprising regenerated cellulose acetate membrane or a polysulfone membrane. However, Shanbrom (EP 0 083 999) disclose the parameters to be used in his ultrafiltration techniques and hence, the use of a regenerated cellulose acetate membrane or a polysulfone membrane constitutes obvious variants of the disclosed ultrafiltration technique.

Finally, the surfactant concentrations recited in claims 14-16 are equally obvious since one of ^{ordinary} skill in the art would optimize disclosed methods.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Robert A. Zeman
January 23, 2003

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